



A DOCPHOENIX

**Advisory Action**

Application No.

09/380,419

Applicant(s)

ROTHSCHILD ET AL.

Examiner

Juliet C Einsmann

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 April 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires four months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_.

Claim(s) objected to: \_\_\_\_.

Claim(s) rejected: 1-12, 20-23, 28-33.

Claim(s) withdrawn from consideration: \_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_.
10. ☐ Other: \_\_\_\_

JEFFREY FREDMAN  
PRIMARY EXAMINER

Continuation of 2. NOTE:

The amendment raises a number of new issues that require further consideration and/or search. Some of these are noted.

1. The amendment to claim 1 broadens the scope of the claim by assaying for a polymorphism anywhere in the MC4R gene, where previously the claims were limited to identifying genotypes characterized by a polymorphism in the seventh transmembrane domain. This broadening of the claim would require further consideration and search.
2. The amendment to claims 2-6 raises new issues under 112 2nd over the recitation "at base 678 of a PCR product" because the base number of the PCR product would be dependent on the primers used.
3. The amendment to claim 29 changes the scope of the claim and would require further consideration and/or search.

Continuation of 5. does NOT place the application in condition for allowance because:

Many of the remarks are directed towards the claims as presented in the amendments filed with the remarks. As these amendments were not entered, these remarks are not addressed herein. Remarks which appear to apply to the pending claims are addressed.

Applicants argue that they have shown that polymorphism in the MC4R gene has been located and is associated with the metabolic traits of fat content, growth rate, and feed consumption in animals. However, as pointed out in the rejections of record, this correlation has only been shown for pigs, not for all animals. Thus, this statement is correct in that pigs are animals, but it is not true to say that applicant has shown this correlation for all animals. Applicants point out that this particular polymorphism is within a highly conserved region among melanocortin receptors and that they have provided an alignment of the predicted amino acid sequences of the pig MC4R with the MC4R protein from other species, demonstrating that the aspartic acid found at position 298 of the seventh transmembrane domain is very highly conserved in the MC4R protein among species. This is not persuasive because there is no correlation between this conservation of sequence and the conservation of polymorphism among species. That is, there is no reason to believe that this same polymorphism would exist in other species. The appearance of polymorphism among different species is highly unpredictable, as discussed in the rejection, and that the protein is conserved among species is not evidence that polymorphic events are also conserved among species.

Applicants argue that they need not understand or disclose how the polymorphism works or how it causes these metabolic traits. However, this is not persuasive. The point here is that if applicant knew that a causative relationship exists between the presence of this polymorphism and the observed traits, then, it may be more reasonable to assume that a similar polymorphism or mutation would be causative of these traits in other species of animals. But in fact, applicant has not disclosed that there is a causative relationship in this case, and in fact it is entirely possible that the disclosed polymorphism is merely a marker of some other genetic feature that is associated with these traits. That such marker relationship would exist in other species is highly unpredictable.

Applicant asserts that the "Examiner has interpreted that experimentation needed in such a way that effectively renders it impossible to claim the claim not only for the instant invention, but for any biological invention." Other inventions are not being examined herein, so the examiner will not comment on "the claim" for any biological invention, but only for the instantly claimed invention. In the instant case, the examiner has not rejected the claims because they do not provide every single example or species covered by the claim, the examiner has rejected the claims because they have large breadth, only single example is provided, and the subject area is highly unpredictable, for all of the reasons discussed herein and in the rejections. This situation differs tremendously from *In re Angstadt*, wherein a large number (forty) examples were provided, only one of which did not work. In this case, the court determined that there was sufficient guidance in an unpredictable art. The court further stated, however, that "each case must be determined by its own facts." In this case, for the reasons discussed herein and in the final office action, the rejection is maintained.